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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,330	04/02/2004	Qi Jia	UNI.26	1136
25871 7590 02/20/2008 SWANSON & BRATSCHEUN, L.L.C. 8210 SOUTHPARK TERRACE LITTLETON, CO 80120			EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 02/20/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/817,330

Applicant(s)

JIA, QI

Examiner

RANDALL WINSTON

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-30,32 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-30,32 and 46-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2007 has been entered.

Claims 19-30, 32, 46-58 and new claim 59 will be examined on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-30, 32 and 46-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (US 6,083,921) in view of Zhou (US 6,319,523).

Applicant claims a pharmaceutical composition (i.e. topical) comprising Free-B-ring flavonoid (i.e. baicalin) , Flavans (i.e. catechin) and excipients in various amounts.

Xu teaches a topical pharmaceutical composition (i.e. the pharmaceutical composition is applied as a cream) comprising baicalin (i.e. the baicalin is extracted from *Scutellaria*) and excipients within a pharmaceutical composition used for antibacterial purposes. Xu, however, does not expressly teach the Flavan of catechin

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included within its pharmaceutical composition used for antibacterial purposes (see, e.g. entire patent including abstract, column 12 lines 25-32 and claims 1 and 7).

Zhou beneficially teaches catechin (i.e. the catechin is extracted from *Acacia catechu*) contained within a pharmaceutical composition used for antibacterial purposes (see, e.g. abstract, claims, especially claims 1 and 5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Xu's topical pharmaceutical composition to include the other active ingredient of catechin as taught in Zhou because the above combined two references would create the claimed topical pharmaceutical to be used for antibacterial purposes. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (e.g. an antibacterial purpose), in order to form a third composition to be used for the same purpose". The adjustments of other conventional working conditions (i.e. the form administered (e.g. the composition is formulated in a regular or controlled releasing vehicle) and in what amounts), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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Please note, the intended use of the above claimed composition (i.e. the pharmaceutical composition for use in the treatment of cyclooxygenase (COX) and (LOX) mediated diseases and inflammatory conditions) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Please note that the patentability of a product (i.e. in claims 24-29) does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Applicant's arguments filed on 11/19/2007 have been carefully considered but they are not deemed persuasive. Applicant argues that the combined two references of Xu and Zhou create a topical pharmaceutical used for antibacterial purposes. Applicant has now amended the claims in a request for continued examination to clarify that the composition of the instant invention is useful for the treatment of cyclooxygenase (COX) and lipooxygenase (LOX) mediated diseases and conditions of the skin. Therefore, neither of the references of Xu or Zhou teaches or suggests the treatment of any of the

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specific diseases and conditions set forth in the specification or claims of the instant invention.

Although Applicant has now amended the claims to clarify that the composition of the instant invention is useful for the treatment of cyclooxygenase (COX) and lipoxygenase (LOX) mediated diseases and conditions of the skin, Applicant's amendment to the claims is not deemed persuasive because the intended use of the above claimed does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Xu's topical pharmaceutical composition to include the other active ingredient of catechin as taught in Zhou because the above combined two references would create the claimed topical pharmaceutical to be used for antibacterial purposes. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (e.g. an antibacterial purpose), in order to form a third composition to be used for the same purpose". The adjustments of other conventional working conditions (i.e. the form administered (e.g. the composition is formulated in a regular or controlled releasing vehicle) and in what amounts), is deemed a matter of

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judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
CHRISTOPHER R. TATE  
PRIMARY EXAMINER